

Defendants.)

Sotera Health provides this Answer based on a reasonable inquiry and its knowledge to-date. Investigation into the matters that are the subject of the Complaint are ongoing. Accordingly, Sotera Health reserves its right to amend, supplement, revise, clarify, or correct the responses set forth below.

1. Sotera Health admits that the Plaintiff has brought this lawsuit against Sterigenics U.S., Sotera Health, LLC, Sotera Health Holdings, LLC and Sotera Health Company. Sotera Health denies that it has caused the State of New Mexico any harm or damages or violated any law as alleged in the Complaint. Sotera Health denies that Plaintiff is entitled to any declaratory, injunctive or monetary relief in this case.

2. The allegations in Paragraph 2 of the Complaint are directed to another Defendant and therefore do not require a response. To the extent that a response is required, Sotera Health admits that Sterigenics U.S., LLC (“Sterigenics U.S.”) is a global leader in comprehensive sterilization solutions meeting industrial sterilization needs in the medical device, pharmaceutical, advanced applications, commercial, and food industries. Except as expressly admitted, the allegations contained in Paragraph 2 are denied.

3. The allegations contained in Paragraph 3 are denied as to Sotera Health. Sotera Health admits that Sterigenics U.S. began operating a sterilization facility in Santa Teresa, New Mexico (the “Facility”) in 1989. Sotera Health admits that the Facility is a major medical products sterilization facility that is responsible for performing essential sterilizations of over 2.5 million medical products each year, including: custom surgical kits, preoperative skin preparation products, surgical drapes and gowns, cardiovascular tubing sets, internal powered surgical staplers, ophthalmic devices, Band-Aids, prefilled syringes, catheters, tubing for ear, nose, and throat, surgical diagnostic equipment, and tracheostomy-coiled-endotracheal tubes. Except as expressly

admitted, the allegations contained in Paragraph 3 are denied, including but not limited to any allegation that Sotera Health LLC, Sotera Health Holdings, LLC or Sotera Heath Company owned or operated the Facility.

4. Sotera Health admits that the Facility operated by Sterigenics U.S. is located at 2400 Airport Road, Santa Teresa, New Mexico 88008. Except as expressly admitted, the allegations contained in Paragraph 4 are denied.

5. Sotera Health presently is without sufficient knowledge or information to form an opinion or belief as to the truth of the allegations in Paragraph 5 of the Complaint, which therefore stand denied.

6. Sotera Health admits that Sterigenics U.S. has used ethylene oxide (“EtO”) in its sterilization operations at the Facility since the Facility began operations in 1989. Except as expressly admitted, the allegations contained in Paragraph 6 are denied.

7. Denied.

8. Sotera Health admits that in 1985 the U.S. Department of Health and Human Services’ (“HHS”) National Toxicology Program published a regulatory document titled, “Fourth Annual Report on Carcinogens” (the “Fourth Annual Report”), which stated that it was prepared as required by and “pursuant to Public Law 95-622.” Sotera Health admits that the Fourth Annual Report listed 148 substances as either “known carcinogens” or substances “which may reasonably be anticipated to be carcinogens.” Sotera Health admits that the Fourth Annual Report did not identify EtO as a “known carcinogen” and included instead EtO on a list of 119 substances “which may reasonably be anticipated to be carcinogenic,” which the Fourth Annual Report defined as “those for which there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals.” Sotera Health admits in 2000 the HHS classified EtO

as “known to be a carcinogen” in its Ninth Report on Carcinogens for the purpose of HHS’s regulatory requirements under 42 U.S.C. 241(b)(4). HHS has emphasized that “[a] listing in the Report does not by itself establish that a substance presents a cancer risk to an individual in daily life.” Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such regulatory classifications, which are in the nature of regulatory opinions, rather than factual matters capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 8 are denied, including but not limited to any allegation that the Fourth Annual Report or Ninth Annual Reports or any studies referenced therein evidence that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

9. Denied.

10. Sotera Health admits only that the U.S. Environmental Protection Agency (“EPA”) published a regulatory review titled, “Evaluation of the Inhalation of Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) In Support of Summary Information on the Integrated Risk Information System (IRIS),” dated December 2016, (“IRIS”) in which the EPA for the first time classified EtO as “carcinogenic to humans” according to the EPA’s regulatory “2005 Guidelines for Carcinogen Risk Assessment.” Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such a regulatory classification, which is in the nature of a regulatory opinion, rather than a factual matter capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific

knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 10 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

11. Denied.

12. Sotera Health admits that IRIS increased its regulatory risk value for a continuous lifetime (24 hours a day for 70 years) of exposure to EtO to approximately 30 times its previous regulatory risk value for a continuous lifetime of exposure to EtO. Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such a regulatory risk value, which is in the nature of a regulatory opinion, rather than a factual matter capable of admission or denial in this Answer, and which is subject to dispute by experts in the relevant fields of scientific knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 12 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

13. Sotera Health admits that IRIS included statements of certain regulatory “Inhalation Unit Risk Estimates” for a continuous lifetime (24 hours a day for 70 years) exposure to EtO. Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the

scientific or medical accuracy of such a regulatory risk estimate, which is in the nature of a regulatory opinion, rather than a factual matter capable of admission or denial in this Answer, and which is subject to dispute by experts in the relevant fields of scientific knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 13 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

14. Sotera Health admits that IRIS stated that it considered a human population study published by certain researchers at the National Institute for Occupational Safety and Health (“NIOSH”) and stated that “the evidence of carcinogenicity from human studies was deemed short of conclusive on its own.” Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of IRIS or the referenced study, which are in the nature of opinions, rather than a factual matter capable of admission or denial in this Answer, which are subject to dispute by experts in the relevant fields of scientific knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 14 are denied, including but not limited to any allegation that IRIS or the referenced study is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that they evidence that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

15. Denied.

16. Denied.

17. Denied.

18. Denied.

19. Denied, including all subparts.

20. Sotera Health admits that the EPA and the New Mexico Environment Department (“NMED”) authorized Sterigenics U.S. to disconnect the Facility’s chamber backvents from the Facility’s abator emissions control system beginning in December 1997, because of the EPA’s safety concerns regarding certain explosion risks found at other EtO sterilization facilities in the United States. Sotera Health admits that Sterigenics U.S. reconnected the backvents at the Facility for Chambers 8, 9, 10 and 13 to its abator emissions control system in 2013 and reconnected its backvents at the Facility for Chambers 1, 2, 3, 4, 5, 6, 7, 11 and 12 to the abator emissions control system in 2014. Sotera Health admits that the Sterigenics U.S. Facility has had very low levels of “fugitive” emissions of EtO, which has been known and authorized by the EPA and NMED. Except as expressly admitted herein, denied.

21. Sotera Health admits that on August 22, 2018, the EPA released an update to the National Air Toxics Assessment (“NATA Update”). Sotera Health admits that the EPA stated, “NATA is a *screening tool*, intended to help EPA and state, local and tribal air agencies determine if areas, pollutants or types of pollution sources need to be examined further to better understand risks to public health.” (emphasis in original). Sotera Health admits that the NATA Update stated that it involved 76,727 census tracts in the “50 U.S. states, Puerto Rico, the Virgin Islands, and the District of Columbia,” and included census tracts in Doña Ana County. Sotera Health admits that for each census tract identified, the NATA Update estimated a regulatory “cancer risk,” which the EPA defined as, “The probability of contracting cancer over the course of a lifetime, assuming

continuous exposure (assumed in NATA to be 70 years).” Except as expressly admitted herein, the allegations in Paragraph 21 are denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company owned or operated Sterigenics U.S.’s Facility or “reported emissions of EtO,” the NATA showed that “the residents of Santa Teresa and surrounding locations are at a statically significant increased risk of developing cancer,” that NATA is reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO, or that NATA evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

22. Sotera Health admits that, from 1996 through 2013, Sterigenics U.S. voluntarily reported to EPA annual total EtO emissions from the Facility ranging from 641 lbs. to 10,082 lbs. Sotera Health admits that from 2014 to 2016, Sterigenics U.S. reported to the EPA annual total EtO emissions from the Facility ranging from 967 lbs. to 5,761 lbs. Except as expressly admitted herein, the allegations in Paragraph 22 are denied.

23. Denied, including any allegation that the Facility’s EtO emissions have increased anyone’s risk of cancer in Doña Ana County and any allegation that Sotera Health has “EtO emissions” from the Facility.

24. Denied.

25. Denied.

26. Denied.

27. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company has emitted ethylene oxide.

28. Sotera Health admits that Sterigenics U.S. has emitted EtO from the Facility as expressly authorized by and in compliance with environmental regulations and the Air Quality Permits the NMED has approved and issued during the history of the Facility's operations. Sotera Health admits that Sterigenics U.S. voluntarily reported the following estimated amounts of EtO emissions permitted under its Air Quality Permits to the EPA from 1994 through 2016:

Year	Total Amount (lbs.)
1994	250
1995	300
1996	641
1997	1,137
1998	5,956
1999	5,318
2000	4,675
2001	5,044
2002	5,026
2003	6,752
2004	7,123
2005	11,756
2006	14,759
2007	14,022
2008	15,439
2009	11,485

2010	12,421
2011	13,068
2012	12,362
2013	10,082
2014	5,761
2015	1,003
2016	967

Sotera Health further admits that Sterigenics U.S. had emissions of EtO from the Facility in compliance with its NMED Air Quality Permits between the years 1989 and 1993. Except as expressly admitted herein, denied, including any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company has reported ethylene oxide emissions from the Facility.

29. Denied.

30. Sotera Health states that it is without knowledge or information sufficient to form a belief concerning the truth of the allegation that “the State’s presuit investigation included sampling of ambient outdoor air within a four-mile radius of the Santa Teresa Plant for EtO,” which therefore stands denied. Sotera Health denies the remaining allegations in Paragraph 30.

31. Sotera Health states that it is without knowledge or information sufficient to form a belief concerning the truth of the allegations in Paragraph 31, which therefore stand denied.

32. Sotera Health states that it is without knowledge or information sufficient to form a belief concerning the truth of the allegations in Paragraph 32, which therefore stand denied.

33. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company emitted ethylene oxide.

34. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company emitted ethylene oxide.

35. Denied.

36. Denied, including but not limited to any allegation that Sterigenics U.S.'s Facility's EtO emissions have increased anyone's risk of adverse health effects or diminished anyone's property values.

37. Sotera Health admits that the State has filed this lawsuit. Otherwise, denied, including but not limited to any allegation that Defendants have engaged in any unlawful conduct or caused anyone any harm as alleged in the Complaint, and any allegation that Plaintiff is entitled to any relief that it seeks in this case.

38. Sotera Health admits that Sterigenics U.S.'s Facility is located in New Mexico. Otherwise, denied.

39. Sotera Health admits that Defendants are foreign companies. Sotera Health denies that venue for this case against Sotera Health in Doña Ana County, New Mexico is proper.

40. Sotera Health admits that this Court has subject matter jurisdiction over this case. Otherwise, denied.

41. Sotera Health denies that the Court has personal jurisdiction over it in this case but has elected to withdraw this defense and defend itself on the merits in this case. Otherwise, denied.

42. Admitted.

43. Sotera Health admits that Attorney General Hector H. Balderas has filed this lawsuit in the name of the State of New Mexico. Otherwise, denied.

44. Sotera Health admits that NMSA 1978 Section 8-5-2 which sets forth "Duties of attorney general," speaks for itself. Otherwise, denied.

45. Denied.

46. Denied, including but not limited to any allegation that Defendants have engaged in any misconduct alleged in the Complaint.

47. The allegations in Paragraph 47 of the Complaint are legal conclusions that do not require a response. To the extent that a response is required, Sotera Health admits that the New Mexico Unfair Practices Act states that the New Mexico Attorney General is authorized to enforce the New Mexico Unfair Practices Act. Sotera Health admits that New Mexico law authorizes the New Mexico Attorney General to bring a civil action to abate a public nuisance under New Mexico's Public Nuisance Statute. Except as expressly admitted herein, denied, including but not limited to any allegation that Sterigenics U.S.'s Facility is a public nuisance or that Sterigenics U.S. or Sotera Health have violated the New Mexico Unfair Practices Act.

48. Admitted.

49. Sotera Health admits that Sotera Health Holdings, LLC is a Delaware limited liability company with a principal place of business in Ohio. Except as expressly admitted herein, denied.

50. Sotera Health admits that it is a Delaware limited liability company that maintains its principal place of business in Ohio. Sotera Health further admits that it was formerly known as Sterigenics International LLC and Sterigenics International, Inc. Except as expressly admitted herein, denied.

51. Sotera Health admits that Sotera Health Company is a publicly held corporation listed on the NASDAQ exchange under ticker symbol SHC. Sotera Health admits that Sotera Health Company was incorporated in Delaware and has a principal place of business in Ohio. Sotera Health admits that Sotera Health Company is the indirect parent company of Sterigenics

U.S. and Sotera Health and is the direct parent company of Sotera Health Holdings, LLC. Except as expressly admitted, denied.

52. Denied.

53. Sotera Health admits that ethylene oxide can be a gas at room temperature at atmospheric pressure. Sotera Health admits that ethylene oxide is colorless and can be flammable. Sotera Health denies that EtO is entirely odorless. Sotera Health admits that EtO is the only method that effectively sterilizes and does not damage numerous medical devices and products during the sterilization process, including but not limited to products that are sensitive to heat or moisture and cannot be sterilized by steam. Except as expressly admitted herein, denied.

54. Admitted.

55. Sotera Health admits that EtO does not persist in air or soil. Sotera Health admits that the EPA has said that EtO has an estimated half-life in air ranging from 69 (during summer months) to 149 days (during winter months). Sotera Health states that it is without information or knowledge sufficient to admit or deny the remainder of the second sentence of Paragraph 55, which therefore stands denied. Sotera Health admits that a World Health Organization (“WHO”) IARC Monograph on EtO has said, “The half-life of ethylene oxide in the atmosphere, assuming ambient concentrations of 5×10^5 hydroxy radicals/cm³, is 211 days. Data suggest that neither rain nor absorption into aqueous aerosols remove ethylene oxide from the atmosphere.” Except as expressly admitted herein, denied.

56. Sotera Health admits that EtO can be a gas at room temperature at atmospheric pressure. Sotera Health admits that EtO has a high vapor pressure and low boiling point. Except as expressly admitted herein, denied.

57. Sotera Health admits that EtO has a high vapor pressure. Sotera Health admits that EtO does not persist in soil, water or air. Except as expressly admitted herein, denied.

58. Sotera Health admits that EtO is heavier than air. Sotera Health admits that the WHO has said that EtO “may travel along the ground; distant ignition possible.” Except as expressly admitted herein, denied.

59. Denied.

60. Denied.

61. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company has owned or operated Sterigenics U.S.’s Facility.

62. Sotera Health denies the allegations in Paragraph 62 related to Sterigenics U.S.’s sterilization facilities, including the Facility. Sotera Health is without knowledge or information sufficient for it to admit or deny the truth of the allegations in Paragraph 62 with respect to facilities that it does not operate, which therefore stand denied.

63. Denied

64. Denied.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Sotera Health admits that certain animal, bacteria and plant studies have reported that EtO has the potential to be genotoxic, damage DNA and be mutagenic in certain circumstances depending on the dose and duration of exposure. Except as expressly admitted herein, denied.

73. Sotera Health states that it presently is without information or knowledge sufficient to admit or deny the allegations in Paragraph 73, which therefore stand denied.

74. Sotera Health admits that in 1985 HHS's National Toxicology Program published its Fourth Annual Report, which stated that it was prepared as required by and "pursuant to Public Law 95-622." Sotera Health admits that the Fourth Annual Report listed 148 substances as either "known carcinogens" or substances "which may reasonably be anticipated to be carcinogens." Sotera Health admits that the Fourth Annual Report did not identify EtO as a "known carcinogen" and included instead EtO on a list of 119 substances "which may reasonably be anticipated to be carcinogenic," which the Fourth Annual Report defined as "those for which there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals." Sotera Health admits in 2000 the HHS classified EtO as "known to be a carcinogen" in its Ninth Report on Carcinogens for the purpose of HHS's regulatory requirements under 42 U.S.C. 241(b)(4). HHS has emphasized that "[a] listing in the Report does not by itself establish that a substance presents a cancer risk to an individual in daily life." Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such regulatory classifications, which are in the nature of regulatory opinions, rather than factual matters capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 74 are denied, including but not limited to any allegation that

the Fourth Annual Report or Ninth Annual Report or any studies referenced therein evidence that any emission of EtO from Sterigenics U.S.'s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

75. Sotera Health admits only that in a 1994 "Monograph" the WHO characterized EtO as "carcinogenic to humans (Group 1)" according to the Monograph's definition of "carcinogenic," based on experimental animal studies and only "*limited evidence* in humans for the carcinogenicity of ethylene oxide." (italics in original). Sotera Health lacks knowledge sufficient to form a belief as to the truth of the assertions in this Monograph, which are in the nature of an opinion rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Sotera Health further responds that the WHO has stated that such a Monograph is only an evaluation of whether an agent is capable of causing cancer "under some circumstances," and that the category "carcinogenic to humans (Group 1)" does not refer to the potency of an agent for causing cancer. Except as expressly admitted herein, the allegations in Paragraph 75 are denied, including but not limited to any allegation that this 1994 Monograph evidences that any emission of EtO from Sterigenics U.S.'s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

76. Sotera Health admits that IRIS made the partially quoted statements in Paragraph 76 of the Complaint. Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such statements, which are in the nature of regulatory opinions, rather than factual matters capable of admission or denial in this Answer, and further, which are subject to dispute by experts in the relevant fields of scientific knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom.

Except as expressly admitted herein, the allegations in Paragraph 76 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from Sterigenics U.S.'s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

77. Sotera Health admits that in 1991 NIOSH published an article titled, "Mortality Among Workers Exposed to Ethylene Oxide" (the "1991 NIOSH Article"), which stated that it studied the occupational exposure of "18,254 workers at 14 plants producing sterilized medical supplies and spices." Sotera Health lacks knowledge sufficient to form a belief as to the truth of the assertions in this article, which are in the nature of opinions rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Sotera Health denies the remaining allegations in Paragraph 77, including but not limited to any allegation that the 1991 NIOSH Article evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

78. Sotera Health admits that IRIS stated, "Although the evidence of carcinogenicity from human studies was deemed short of conclusive on its own, EtO is characterized as 'carcinogenic to humans' by the inhalation route of exposure based on the total weight of evidence, in accordance with the U.S. Environmental Protection Agency's (EPA's) 2005 *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a)." Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of this statement, which is in the nature of a regulatory opinion, rather than a factual matter capable of admission or

denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 78 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from Sterigenics U.S.'s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

79. Denied.

80. Sotera Health admits that IRIS said that its confidence in its regulatory "hazard characterization of EtO as 'carcinogenic to humans' is high." Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of that statement, which is in the nature of a regulatory opinion, rather than a factual matter capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 80 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from Sterigenics U.S.'s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

81. Sotera Health admits that the EPA made the regulatory statement in IRIS that EtO is carcinogenic to humans for the first time in December 2016. Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of

that regulatory classification, which is in the nature of a regulatory opinion, rather than a factual matter capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 81 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from Sterigenics U.S.'s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

82. Sotera Health admits that IRIS was an EPA regulatory evaluation of the carcinogenicity of EtO. Sotera Health admits that IRIS stated that “in accordance with the U.S. Environmental Protection Agency’s (EPA’s) Guidelines for Carcinogen Risk Assessment,” it characterized EtO as “carcinogenic to humans” and said that a “mutagenic mode of action is operative in EtO carcinogenicity.” Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such statements, which are in the nature of regulatory opinions, rather than factual matters capable of admission or denial in this Answer, and further, which are subject to dispute by experts in the relevant fields of scientific knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 82 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from Sterigenics U.S.'s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

83. Denied.

84. Sotera Health admits that IRIS increased its regulatory risk value for a continuous lifetime (24 hours a day for 70 years) of exposure to EtO to approximately 30 times its previous regulatory risk value for a continuous lifetime of exposure to EtO. Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of that regulatory risk estimate, which is in the nature of a regulatory opinion, rather than a factual matter capable of admission or denial in this Answer, and further, which is subject to dispute by experts in the relevant fields of scientific knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 84 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from Sterigenics U.S.'s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

85. Denied.

86. Denied.

87. Sotera Health admits that Sterigenics U.S. began its sterilization operations using EtO at the Facility in 1989. Sotera Health states that Sterigenics U.S. has safely emitted low levels of EtO from its sterilization operations in compliance with environmental regulations and its Air Quality Permits issued by the NMED during the Facility's existence. Except as expressly admitted herein, denied.

88. Sotera Health admits that, in August 1977, the NIOSH issued a “Special Occupational Hazard Review with Control Recommendations” for the “Use of Ethylene Oxide as a Sterilant in Medical Facilities.” Except as expressly admitted, denied.

89. Sotera Health admits that NIOSH’s August 1977 “Special Occupational Hazard Review with Control Recommendations” for the “Use of Ethylene Oxide as a Sterilant in Medical Facilities” stated, “Ethylene oxide (ETO) is used extensively within health care facilities for sterilization of equipment and supplies which are heat sensitive. It is unique for this purpose. Alternative chemicals or processes have, in themselves, serious limitations or health hazards. NIOSH recognizes, therefore, that the continued use of ETO as a gaseous sterilant is highly desirable in many situations. Recent results of tests for mutagenesis have increased the concern for potential health hazards associated with exposure to ETO. In order to assess the potential for exposure and hazards, NIOSH has undertaken this Special Occupational Hazard Review.” Sotera Health lacks knowledge or information sufficient to form a belief as to the truth of those assertions concerning occupational exposures to EtO made in this report, which are in the nature of regulatory opinions rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, Sotera Health denies the allegations in Paragraph 89, including but not limited to any allegation that the referenced NIOSH publication or any studies referenced therein evidence that any emission of EtO from Sterigenics U.S.’s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

90. Sotera Health admits that NIOSH’s August 1977 “Special Occupational Hazard Review with Control Recommendations” for the “Use of Ethylene Oxide as a Sterilant in Medical

Facilities” makes the statement quoted in Paragraph 90 of the Complaint. Sotera Health lacks knowledge or information sufficient to form a belief as to the truth of those assertions concerning occupational exposures to EtO made in this report, which are in the nature of opinions rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, Sotera Health denies the allegations in Paragraph 90, including but not limited to any allegation that the referenced NIOSH publication or any studies referenced therein evidence that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

91. Sotera Health admits that NIOSH’s August 1977 “Special Occupational Hazard Review with Control Recommendations” for the “Use of Ethylene Oxide as a Sterilant in Medical Facilities” stated, “No definitive epidemiological studies, and no standard long-term carcinogenesis assays, are available on which to assess carcinogenic potential. Limited tests by skin application or subcutaneous injections in mice did not reveal carcinogenicity. However, the alkylating and mutagenic properties of ETO are sufficient bases for concern about its potential carcinogenicity.” Sotera Health lacks knowledge or information sufficient to form a belief as to the truth of those assertions concerning occupational exposures to EtO made in this report, which are in the nature of opinions rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, Sotera Health denies the allegations in Paragraph 91, including but not limited to any allegation that the referenced NIOSH publication or any studies referenced therein evidence that

any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

92. Sotera Health admits that, after recognizing that “[n]o definitive epidemiological studies, and no standard long-term carcinogenesis assays, are available on which to assess carcinogenic potential. Limited tests by skin application or subcutaneous injections in mice did not reveal carcinogenicity,” NIOSH’s August 1977 “Special Occupational Hazard Review with Control Recommendations” for the “Use of Ethylene Oxide as a Sterilant in Medical Facilities” said that “the alkylating and mutagenic properties of ETO are sufficient bases for concern about its potential carcinogenicity” and recommended that “EtO be considered as mutagenic and potentially carcinogenic to humans, and that occupational exposure to be minimized” Sotera Health lacks knowledge or information sufficient to form a belief as to the truth of those assertions concerning occupational exposures to EtO made in this report, which are in the nature of opinions rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, Sotera Health denies the allegations in Paragraph 92, including but not limited to any allegation that the referenced NIOSH publication or any studies referenced therein evidence that any emission of EtO from Sterigenics U.S.’s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

93. Denied.

94. Sotera Health admits that NIOSH’s August 1977 “Special Occupational Hazard Review with Control Recommendations” for the “Use of Ethylene Oxide as a Sterilant in Medical Facilities” stated its regulatory opinion that reasons for unnecessary occupational exposure of

persons working in sterilization facilities to EtO includes “inadequate ventilation of sterilizers,” “poor design of the sterilization facility.” Sotera Health lacks knowledge or information sufficient to form a belief as to the truth of those assertions concerning occupational exposures to EtO made in this report, which are in the nature of regulatory opinions rather than factual materials capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, Sotera Health denies the allegations in Paragraph 94, including but not limited to any allegation that the referenced NIOSH publication or any studies referenced therein evidence that any emission of EtO from Sterigenics U.S.’s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

95. Sotera Health admits that, in May 1981, NIOSH released Current Intelligence Bulletin 35, entitled “Ethylene Oxide (ETO): Evidence of Carcinogenicity,” in which NIOSH “recommend[ed] that ethylene oxide be regarded in the workplace as a potential occupational carcinogen, and that appropriate controls be used to reduce worker exposure.” Sotera Health lacks knowledge or information sufficient to form a belief as to the truth of those assertions concerning occupational exposures to EtO made in this report, which are in the nature of regulatory opinions rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, Sotera Health denies the allegations in Paragraph 95, including but not limited to any allegation that the referenced NIOSH publication or any studies referenced therein evidence that any emission of EtO from Sterigenics

U.S.'s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

96. Sotera Health admits that in 1985 the HHS National Toxicology Program published its Fourth Annual Report, which is a regulatory document that stated that it was prepared as required by and “pursuant to Public Law 95-622.” Sotera Health admits that the Fourth Annual Report listed 148 substances as either “known carcinogens” or substances “which may reasonably be anticipated to be carcinogens.” Sotera Health admits that the Fourth Annual Report did not identify EtO as a “known carcinogen” and included instead EtO on a list of 119 substances “which may reasonably be anticipated to be carcinogenic,” which the Fourth Annual Report defined as “those for which there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals.” Sotera Health admits that in 1987 California Proposition 65 included EtO on its list of chemicals that it said cause cancer, for regulatory purposes. Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such regulatory classifications, which are in the nature of regulatory opinions, rather than factual matters capable of admission or denial in this Answer, and further, which are subject to dispute by experts in the relevant fields of scientific knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 96 are denied, including but not limited to any allegation that the Fourth Annual Report or California Proposition 65 evidence that any emission of EtO from Sterigenics U.S.'s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

97. Sotera Health admits that Sterigenics U.S. operated two sterilization facilities using EtO in California in 1987 and that it was aware that EtO was regulated under California Proposition

65 in 1987. Except as expressly admitted herein, the allegations in Paragraph 97 are denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company operated sterilization facilities in California and that California Proposition 65 evidences that any emission of EtO from Sterigenics U.S.'s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

98. Sotera Health admits that the 1991 NIOSH Article stated that it studied the occupational EtO exposure of "18,254 workers at 14 plants producing sterilized medical supplies and spices." Sotera Health admits that workers at Sterigenics U.S.'s Willowbrook, IL sterilization facility were included among the workers in the study. Sotera Health lacks knowledge sufficient to form a belief as to the truth of the assertions in the 1991 NIOSH Article, which are in the nature of opinions rather than factual material capable of admission or denial in this Answer and which are subject to dispute by experts in the relevant fields, and denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Sotera Health denies the remaining allegations of Paragraph 98, including but not limited to any allegation that the 1991 NIOSH Article evidences that any emission of EtO from Sterigenics U.S.'s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

99. Denied.

100. Sotera Health admits that Kathy Hoffman sent the EPA's Science Advisory Board a letter dated November 12, 2014. Sotera Health admits that Ms. Hoffman was Sterigenics U.S.'s Senior Vice President of Global Environmental, Health & Safety at the time of sending this letter. Except as expressly admitted herein, denied.

101. Denied as stated.

102. Denied.

103. Sotera Health admits that IRIS relied on NIOSH studies and categorized EtO as “carcinogenic to humans” for regulatory purposes for the first time in December 2016. Sotera Health lacks sufficient knowledge or information to form a belief as to the truth of the scientific or medical accuracy of such regulatory positions, which are in the nature of regulatory opinions, rather than factual matters capable of admission or denial in this Answer, and further, which are subject to dispute by experts in the relevant fields of scientific knowledge. Sotera Health denies any inference of wrongdoing or liability that may be claimed to arise therefrom. Except as expressly admitted herein, the allegations in Paragraph 103 are denied, including but not limited to any allegation that IRIS is a reliable or accurate assessment of any cancer hazard or risk associated with exposure to EtO and any allegation that it evidences that any emission of EtO from the Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

104. Denied as stated.

105. Sotera Health admits that Jeffrey Shuren, as director of the FDA’s Center for Devices and Radiological Health, sent Rick Keigwin, Director of the Office of Pesticide Programs of the EPA, a February 5, 2020 letter in response to outreach from the EPA. Sotera Health admits that Jeffrey Shuren’s February 5, 2020 letter stated, “EPA should establish EtO emissions limits based on the levels necessary to protect human health and the environment from EtO toxicity.” Except as expressly admitted, denied.

106. Sotera Health admits that Jeffrey Shuren’s February 5, 2020 letter referenced in Paragraph 105 of the Complaint stated, “Today, about fifty percent of all sterile medical devices in the U.S. are sterilized with EtO” and “FDA looks to EPA to set allowable limits for EtO

emissions since FDA does not have the authority to do so. Contract sterilizers and medical device manufacturers must comply with the EtO standards and guidelines that EPA sets and FDA is committed to working with these entities to reduce the amount of EtO used and to explore the use of alternatives as appropriate. If a facility is unable to meet EPA emissions limits and its inability to do so could lead to product availability concerns, FDA will work with the facility and other entities in the supply chain to mitigate these concerns.” Except as expressly admitted, denied.

107. Denied.

108. Denied.

109. Sotera Health admits that Sterigenics U.S.’s Facility is located in a remote industrial area that is approximately 2 miles from the nearest school or neighborhood and approximately 2.5 miles from the nearest church. Sotera Health states that it is without information or knowledge sufficient to admit or deny the truth of the remaining allegations in Paragraph 109, which therefore stand denied.

110. Sotera Health admits that Sterigenics U.S.’s Facility emitted the following estimated amounts of EtO emissions in compliance with environmental regulations and its Air Quality Permits from the NMED from 1994 through 2016:

Year	Total Amount (lbs.)
1994	250
1995	300
1996	641
1997	1,137
1998	5,956
1999	5,318

2000	4,675
2001	5,044
2002	5,026
2003	6,752
2004	7,123
2005	11,756
2006	14,759
2007	14,022
2008	15,439
2009	11,485
2010	12,421
2011	13,068
2012	12,362
2013	10,082
2014	5,761
2015	1,003
2016	967

Sotera Health admits that Sterigenics U.S. had emissions of EtO from Sterigenics U.S.'s Facility in compliance with its NMED Air Quality Permits between the years 1989 and 1993 and from 2017 to present. Except as expressly admitted herein, denied, including allegation that any

emission of EtO from Sterigenics U.S.'s Facility caused anyone to develop or be at an increased risk of developing cancer or other medical condition as alleged in the Complaint.

111. Sotera Health admits that Sterigenics U.S. voluntarily reported Sterigenics U.S.'s Facility's estimated EtO emissions under its Air Quality Permits to the EPA from at least 1994 to 2016. Sotera Health admits that Sterigenics U.S. has not reported estimates of the Facility's low level EtO emissions to the EPA's Toxics Release Inventory program from 2017 to present and that such reporting is not required by the EPA. Except as expressly admitted herein, denied.

112. Denied.

113. Sotera Health admits that Sterigenics U.S. voluntarily reported to the EPA the following estimated amounts of EtO emissions from Sterigenics U.S.'s Facility under its Air Quality Permits from the NMED from 1994 through 2016:

Year	Total Amount (lbs.)
1994	250
1995	300
1996	641
1997	1,137
1998	5,956
1999	5,318
2000	4,675
2001	5,044
2002	5,026
2003	6,752

2004	7,123
2005	11,756
2006	14,759
2007	14,021
2008	15,439
2009	11,485
2010	12,421
2011	13,069
2012	12,362
2013	10,082
2014	5,761
2015	1,003
2016	967

Except as expressly admitted herein, denied.

114. Sotera Health admits that fugitive emissions from Sterigenics U.S.'s Facility were very low amounts. Except as expressly admitted herein, denied.

115. Denied.

116. Sotera Health admits that records reflect the following estimated amounts of EtO were used at Sterigenics U.S.'s Facility in the years shown:

Period	Amount (lbs.)
1996	405,875

1997	442,726
1998	446,895
1999	399,064
2000	391,918
2001	422,823
2002	421,340
2003	541,784
2004	606,964
2005	771,087
2006	968,009
2007	919,635
2008	1,012,606
2009	1,035,160
2010	1,001,320
2011	1,055,102
2012	1,128,330
2013	1,034,298
2014	1,010,601
2015	1,008,672
2016	1,015,733
2017	998,570
2018	1,086,463

2019	1,092,940
2020	1,089,769

Except as expressly admitted herein, denied.

117. Sotera Health admits that the EPA and NMED authorized Sterigenics U.S. to disconnect the Facility's chamber backvents from the Facility's abator emissions control system beginning in December 1997, because of the EPA's safety concerns regarding certain explosion risks found at other EtO sterilization facilities in the United States. Sotera Health admits that Sterigenics U.S. reconnected the backvents for Chambers 8, 9, 10 and 13 to its abator emissions control system in 2013 and reconnected the backvents for Chambers 1, 2, 3, 4, 5, 6, 7, 11 and 12 to the abator emissions control system in 2014. Sotera Health admits that during the time when the Facility's backvents were not routed to the Facility's abator emission control system pursuant to the EPA's authorization, the Facility had very low levels of "fugitive" emissions of EtO from the Facility, which was known and authorized by the EPA and NMED. Except as expressly admitted herein, denied.

118. Sotera Health states that it is without knowledge or information sufficient to admit or deny the allegation in Paragraph 118 that a "former Sterigenics employee" told Plaintiff what is alleged in Paragraph 118, which therefore stands denied. Sotera Health denies the remaining allegations in Paragraph 118.

119. Denied.

120. Denied.

121. Sotera Health states that it is without knowledge or information sufficient to admit or deny the allegation in Paragraph 121 that a "former Sterigenics employee" told Plaintiff what

is alleged in Paragraph 121, which therefore stands denied. Sotera Health denies the remaining allegations in Paragraph 121.

122. Sotera Health states that it is without knowledge or information sufficient to admit or deny the allegation in Paragraph 122 that a “former employee” indicated to Plaintiff what is alleged in Paragraph 122, which therefore stands denied. Sotera Health denies the remaining allegations in Paragraph 122.

123. Sotera Health states that it is without knowledge or information sufficient to admit or deny the allegation in Paragraph 123 that a “former Sterigenics employee” indicated to Plaintiff what is alleged in Paragraph 123, which therefore stands denied. Sotera Health denies the remaining allegations in Paragraph 123.

124. Denied.

125. Denied.

126. Denied.

127. Sotera Health admits that on August 22, 2018, the EPA released the NATA Update. Except as expressly admitted herein, denied.

128. Denied.

129. Sotera Health admits that the NATA update used emissions data from 2014. Except as expressly admitted herein, denied.

130. Sotera Health admits that Sterigenics U.S. voluntarily reported to the EPA the following estimated amounts of EtO emissions from Sterigenics U.S.’s Facility for 2011 through 2014:

Year	Total Amount (lbs.)
2011	13,068

2012	12,362
2013	10,082
2014	5,761

Except as expressly admitted herein, denied.

131. Denied.

132. Denied.

133. Sotera Health admits that in 2014 Sterigenics U.S.'s Facility emitted an estimated 5,761 lbs. of EtO and Sterigenics U.S. voluntarily reported those estimated emissions to the EPA. Sotera Health admits that 5,761 lbs. is 2.8805 tons. Sotera Health denies the remaining allegations in Paragraph 133 and its subparts.

134. Denied.

135. Denied.

136. Sotera Health states that it presently is without information or knowledge sufficient to admit or deny the allegations in Paragraph 136 of the Complaint, which therefore stand denied.

137. Sotera Health states that it presently is without information or knowledge sufficient to admit or deny the allegations in Paragraph 137 of the Complaint, which therefore stand denied.

138. Denied.

139. Denied.

140. Denied.

141. Denied.

142. Denied.

143. Denied.

144. Denied.

145. Sotera Health admits that the NMED issued Sterigenics U.S. an Air Quality Permit for the Facility in 1989. Sotera Health admits that the NMED issued modifications to the Facility's Air Quality Permit. Sotera Health admits that the NMED Air Quality Permits and Air Quality Permit modifications included emissions authorizations, reporting requirements, emissions control approvals and requirements, and other requirements and approvals. Except as expressly admitted herein, denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have owned or operated the Facility or have received any permit as alleged in Paragraph 145.

146. Denied.

147. Denied, including all subparts.

148. Denied.

149. Denied.

150. Sotera Health admits that Sterigenics U.S. has contracts with its sterilization customers who pay Sterigenics U.S. for its sterilization services. Except as expressly admitted herein, denied.

151. Sotera Health admits that Sterigenics U.S. has publicly acknowledged and explained that its EtO sterilization operations are safe to the environment and others. Except as expressly admitted herein, denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have clients or sterilization and fumigation operations.

152. Sotera Health admits that Sterigenics U.S.'s environmental policy, as stated on its website, is that it is "dedicated to protecting the environment and our communities. Our facilities adhere to Environmental Management Systems (EMS) of established requirements and standards.

We focus on continuous improvements and eliminating risk to protect people, the environment, and property. Our EMS meet or exceed compliance requirements set by our regulators.” Except as expressly admitted herein, denied.

153. Sotera Health admits that the Sotera Health 2017 Global Health Corporate Sustainability and Social Responsibility Report includes the recognitions partially quoted in Paragraph 153. Except as expressly admitted herein, denied.

154. Sotera Health admits that Sterigenics U.S. has recognized and informed the public of the fact that Sterigenics U.S.’s sterilization facilities using EtO are safe for the environment. Except as expressly admitted herein, denied.

155. Sotera Health admits that Sterigenics U.S.’s website states its “Unwavering Commitment to Safety and the Environment.” Sotera Health admits that Sterigenics U.S.’s website has at times between August 2014 and February 2018 contained the statements partially quoted in Paragraph 155 of the Complaint. Except as expressly admitted herein, denied.

156. Sotera Health admits that Sterigenics U.S. stated its commitment to safety and the environment on its website as partially quoted in Paragraph 155 of the Complaint and in other public statements recognizing that commitment. Except as expressly admitted herein, denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have had any customers or sterilization operations.

157. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have emitted ethylene oxide from Sterigenics U.S.’s Facility.

158. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have emitted ethylene oxide from Sterigenics U.S.'s Facility.

FIRST CAUSE OF ACTION
PUBLIC NUISANCE

159. Sotera Health incorporates by reference its responses to Paragraphs 1 through 158 of the Complaint as if stated fully herein.

160. Paragraph 160 states a legal conclusion to which a response is not required. To the extent a response is required, denied.

161. Denied.

162. Denied.

163. Denied.

164. Denied.

165. Denied.

166. Denied, including but not limited any allegation that Sterigenics U.S.'s Facility's permitted and safe emissions of EtO are toxic, endanger anyone's health, or degrade the quality of air.

167. Denied.

168. Denied, including but not limited to any allegation that Sterigenics U.S.'s Facility has harmed New Mexico's rights or interests or caused New Mexico any inconvenience.

169. Denied.

170. Denied.

171. Denied.

172. Denied.

173. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have emitted ethylene oxide from Sterigenics U.S.'s Facility.

174. Denied.

175. Denied.

176. Denied.

177. Denied, including but not limited to any allegation that Sterigenics U.S.'s Facility has caused any medical disorders and denies that Plaintiff is entitled to the order and monitoring program it seeks in Paragraph 177 of the Complaint.

178. Denied.

SECOND CAUSE OF ACTION
VIOLATIONS OF THE NEW MEXICO PUBLIC NUISANCE STATUTE,
NMSA 1978 §§ 30-8-1, *ET SEQ.*

179. Sotera Health incorporates by reference its responses to Paragraphs 1 through 178 of the Complaint as if stated fully herein.

180. Paragraph 180 states a legal conclusion to which a response is not required. To the extent a response is required, denied.

181. Paragraph 181 states a legal conclusion to which a response is not required. To the extent a response is required, Sotera Health states that Plaintiff has asserted a purported claim under New Mexico's public nuisance statute but denies that Plaintiff has stated a claim for a violation of the statute in this case. Except as expressly admitted herein, denied.

182. Sotera Health admits that NMSA 30-8-1 states, "A public nuisance consists of knowingly creating, performing or maintain anything affecting any number of citizens without lawful authority which is either: A. injurious to public health, safety, morals or welfare; or B. interferes with the exercise and enjoyment of public rights, including the right to use public

property. Whoever commits a public nuisance for which the act or penalty is not otherwise prescribed by law is guilty of a petty misdemeanor.” Except as expressly admitted herein, denied.

183. Sotera Health admits that New Mexico law generally authorizes the New Mexico Attorney General to bring a civil action to abate a public nuisance under New Mexico’s Public Nuisance Statute. Except as expressly admitted herein, denied, including but not limited to any allegation that Sterigenics U.S.’s Facility is a public nuisance or that Defendants have violated New Mexico’s Public Nuisance Statute.

184. Denied.

185. Denied.

186. Denied.

187. Denied.

188. Denied.

189. Denied.

190. Denied, including but not limited to any allegation that Sterigenics U.S.’s Facility’s permitted and safe emissions of EtO are toxic, endanger anyone’s health, or degrade the quality of air.

191. Denied.

192. Denied, including but not limited to any allegation that Sterigenics U.S.’s Facility has harmed New Mexico’s rights or interests or caused New Mexico any inconvenience.

193. Denied.

194. Denied.

195. Denied.

196. Denied.

197. Denied.

198. Denied.

199. Denied.

200. Denied.

201. Denied, including but not limited to any allegation that Sterigenics U.S.'s Facility has caused any medical disorders and denies that Plaintiff is entitled to the order and monitoring program it seeks in Paragraph 201 of the Complaint.

202. Denied.

THIRD CAUSE OF ACTION
STRICT LIABILITY

203. Sotera Health incorporates by reference its responses to Paragraphs 1 through 202 of the Complaint as if stated fully herein.

204. Denied.

205. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company operated Sterigenics U.S.'s Facility.

206. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have emitted ethylene oxide from Sterigenics U.S.'s Facility.

207. Denied.

208. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have emitted ethylene oxide from Sterigenics U.S.'s Facility.

209. Denied.

210. Denied.

211. Denied.

212. Denied.

FOURTH CAUSE OF ACTION
NEGLIGENCE

213. Sotera Health incorporates by reference its responses to Paragraphs 1 through 212 of the Complaint as if stated fully herein.

214. Denied.

215. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have operated or emitted ethylene oxide from Sterigenics U.S.'s Facility.

216. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have emitted ethylene oxide from Sterigenics U.S.'s Facility.

217. Denied.

218. Denied, including that Sterigenics U.S.'s permitted emissions of EtO are toxic and any allegation that Defendants breached a legal duty to anyone in this case.

219. Denied.

220. Denied.

221. Denied.

222. Denied.

FIFTH CAUSE OF ACTION
TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

223. Sotera Health incorporates by reference its responses to Paragraphs 1 through 222 of the Complaint as if stated fully herein.

224. Denied.

225. Denied.

226. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have emitted ethylene oxide from Sterigenics U.S.'s Facility.

227. Denied.

228. Denied.

229. Denied.

230. Denied.

231. Denied.

SIXTH CAUSE OF ACTION
VIOLATIONS OF NEW MEXICO UNFAIR PRACTICES ACT,
1978 NMSA §§ 57-12-1, *ET SEQ.*

232. Sotera Health incorporates by reference its responses to Paragraphs 1 through 231 of the Complaint as if stated fully herein.

233. Denied.

234. Admitted.

235. Sotera Health admits that NMSA §§57-12-2(D) says, “‘unfair or deceptive trade practice’ means an act specifically declared unlawful pursuant to the Unfair Practices Act, a false or misleading oral or written statement, visual description or other representation of any kind knowingly made in connection with the sale, lease, rental or loan of goods or services or in the extension of credit or in the collection of debts by a person in the regular course of the person’s trade or commerce, that may, tends to or does deceive or mislead any person and includes” the acts specifically enumerated in NMSA § 57-12-2(D). Except as expressly admitted herein, denied.

236. Sotera Health admits that NMSA § 57-12-2(D) defines an unfair or deceptive trade practice to include, “if made in connection with the sale, lease, rental or loan of goods or services,”

“representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that the person does not have,” “representing that goods or services are of a particular standard, quality or grade or that goods are of a particular style or model if they are of another” and “using exaggeration, innuendo or ambiguity as to a material fact or failing to state a material fact if doing so deceives or tends to deceive.” Except as expressly admitted herein, denied.

237. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have used ethylene oxide or had sterilization or fumigation operations.

238. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have used ethylene oxide or had sterilization or fumigation operations.

239. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company emitted ethylene oxide from Sterigenics U.S.’s Facility.

240. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company emitted ethylene oxide from Sterigenics U.S.’s Facility.

241. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have used ethylene oxide or had sterilization or fumigation operations.

242. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have used ethylene oxide or had sterilization or fumigation operations.

243. Denied, including but not limited to any allegation that Sotera Health, Sotera Health Holdings, LLC or Sotera Health Company have had sterilization customers or clients.

244. Sotera Health denies that Plaintiff is entitled to any relief that it seeks in Paragraph 244 of the Complaint.

Sotera Health denies that Defendants have violated the Unfair Practice Act and that Plaintiff is entitled to any relief requested in Plaintiff's prayer for relief.

Except as expressly and specifically admitted herein, Sotera Health denies the allegations set forth in Plaintiff's Complaint.

DEFENSES

Without admitting or acknowledging that Sotera Health bears the burden of proof as to any of them, Sotera Health asserts the following defenses:

FIRST DEFENSE

The Complaint and each cause of action contained therein fails to state a claim upon which relief can be granted.

SECOND DEFENSE

Plaintiff has failed to provide a reasonable statement of a claim for relief against Sotera Health. Sotera Health does not have reasonable notice of the time, place, nature, and manner of the claimed wrongs by Sotera Health as they relate to Plaintiff's alleged damages. Therefore, Plaintiff has failed to state a claim against Sotera Health upon which relief can be granted.

THIRD DEFENSE

Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and/or repose.

FOURTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver, estoppel, *res judicata*, laches, and unclean hands.

FIFTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because Sotera Health has acted reasonably, in good faith, and with the skill, prudence, and diligence exercised by others.

SIXTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because Sotera Health did not owe or breach any legal duty to Plaintiff as alleged in the Complaint.

SEVENTH DEFENSE

Plaintiff's claims may be preempted or barred, in whole or in part, expressly or impliedly, by state and federal law and regulations, including but not limited to the Federal Food, Drug and Cosmetic Act and the Medical Device Amendments of 1976, *e.g.*, 21 U.S.C. §§ 337(a), 360k(a), the Clean Air Act, 42 U.S.C. § 7401 *et seq.*, and the New Mexico Air Quality Control Act, and their implementing regulations, along with any state and federal air quality permits for regulated air emissions.

EIGHTH DEFENSE

Any EtO emitted at Sterigenics U.S.'s facility in connection with its sterilization of medical products was emitted as authorized by, and in conformity with, the applicable laws and regulations, prevailing state of the art standards, and prevailing standards of the industry.

NINTH DEFENSE

Any emissions of EtO by Sterigenics U.S., as authorized by both state and federal regulators, are not properly the subject of a public nuisance claim.

TENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because the sterilization of medical products using EtO is not an "ultrahazardous and/or abnormally dangerous activity" as alleged in the Complaint.

ELEVENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because the social utility and benefit of Sterigenics U.S.'s sterilization of medical products with EtO outweighs any risk of danger and/or harm, if any.

TWELFTH DEFENSE

At all times material to Plaintiff's claims, the state of medical and scientific knowledge did not provide Sotera Health with either knowledge or reason to know of a foreseeable risk of harm to Plaintiff stemming from Sterigenics U.S.'s sterilization facility.

THIRTEENTH DEFENSE

There is a lack of joinder of one or more parties who should or must be joined in this action.

FOURTEENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff's injuries, if any, were the result of actions or circumstances, or persons, entities, or conditions, unforeseeable to Defendants and beyond their control.

FIFTEENTH DEFENSE

Any putative claims available to Plaintiff but not joined in this action are barred for failure to assert those claims in the Complaint.

SIXTEENTH DEFENSE

No injury or damage allegedly suffered by Plaintiff, if any, was legally or proximately caused by any alleged act or omission on the part of Sotera Health.

SEVENTEENTH DEFENSE

Sotera Health pleads its rights to contribution and/or indemnity.

EIGHTEENTH DEFENSE

Sotera Health denies that it has any liability to Plaintiff, but, to the extent that Plaintiff can or has failed to avail itself of funds from unnamed third parties, including, without limitation insurance companies and unnamed potentially responsible parties, Sotera Health may be entitled to a set-off in the amount of such funds including interest.

NINETEENTH DEFENSE

Plaintiff's claims may be barred, in whole or in part, to the extent that it has released, settled, entered into an accord and satisfaction, or otherwise compromised the causes of action in its Complaint.

TWENTIETH DEFENSE

Plaintiff's claims are barred, in whole or in part, to the extent that the injuries alleged were caused by the acts or omissions of a third party and not Defendants.

TWENTY-FIRST DEFENSE

Plaintiff's claims are barred, in whole or in part, to the extent that the acts and/or omissions of persons or entities other than Sotera Health, over whom Sotera Health had no control, were intervening or superseding causes of the injuries alleged by Plaintiff.

TWENTY-SECOND DEFENSE

Any claim that liability for any of Plaintiff's alleged injuries and damages should be based upon a concert of action, enterprise liability or market share liability theory is contrary to the fact that such theories are not recognized under the law of this jurisdiction and, if applied by the Court here, would deny Sotera Health its rights of equal protection of the law and due process of law.

TWENTY-THIRD DEFENSE

Plaintiff has not suffered any injury which allow it to assert or recover on the causes of action in the Complaint.

TWENTY-FOURTH DEFENSE

If Plaintiff sustained any injury or damage, which Sotera Health denies, then such injury or damage was proximately caused or contributed to by other factors and not by EtO used to sterilize medical equipment at Sterigenics U.S.'s facility.

TWENTY-FIFTH DEFENSE

If Plaintiff sustained any injury or damage as a result of EtO in the atmosphere, which Sotera Health denies, then such injury or damage was caused by EtO from sources other than emissions attributable to Sterigenics U.S.'s facility, including but not limited to, endogenously produced EtO.

TWENTY-SIXTH DEFENSE

Plaintiff's claims may be barred, reduced, and/or limited pursuant to applicable statutory and common law regarding limitation of awards, caps on recovery, and set-offs.

TWENTY-SEVENTH DEFENSE

Plaintiff's claim for punitive damages fails as a matter of law.

TWENTY-EIGHTH DEFENSE

Plaintiff is not entitled to punitive damages because no act or omission of Sotera Health shows malice, willfulness, recklessness, wantonness, fraud, or bad faith.

TWENTY-NINTH DEFENSE

Sotera Health may not be found liable for punitive damages where the conditions which form the basis of Plaintiff's claims are, and have been, the subject of state or federal regulatory action or oversight, and when there has been substantial compliance with the findings, orders, and directives of the responsible regulatory agency.

THIRTIETH DEFENSE

Plaintiff's claim for punitive damages is barred in whole or in part by applicable state and federal law.

THIRTY-FIRST DEFENSE

Plaintiff's claim for punitive damages is barred by the Due Process Clause and Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution, the prohibition of excessive fines contained in the Eighth Amendment to the U.S. Constitution, and the Double Jeopardy Clause of the Fifth Amendment.

THIRTY-SECOND DEFENSE

Plaintiff's claim for punitive damages is barred by Article II, Section 18 of the Constitution of the State of New Mexico, which guarantees that no person shall be deprived of life, liberty, or property without due process of law; Article II, Section 4 of the Constitution of the State of New Mexico, which guarantees that no person shall be denied the equal protection of the laws; and Article II, Section 13 of the Constitution of the State of New Mexico, which prohibits the imposition of excessive fines.

THIRTY-THIRD DEFENSE

Plaintiff's claim for punitive damages is barred because any actions and operations alleged in this case complied with all relevant and applicable federal and state laws and regulations and with industry customs and standards.

THIRTY-FOURTH DEFENSE

Plaintiff's claim for punitive damages is barred because Sotera Health lacked notice that its alleged conduct could subject it to punishment.

THIRTY-FIFTH DEFENSE

Plaintiff's claim for punitive damages is preempted by federal law.

THIRTY-SIXTH DEFENSE

Plaintiff's claims for special damages are barred because they are not specifically stated or pled with particularity, and Plaintiff cannot prove the required elements to recover such damages.

THIRTY-SEVENTH DEFENSE

There is no statute providing for Plaintiff's strict liability claim and, therefore, said claim fails to state a claim upon which relief can be granted.

THIRTY-EIGHTH DEFENSE

Plaintiff's strict liability claim is barred as a matter of law because such a claim based on the allegations in the Complaint has not been recognized by New Mexico law.

THIRTY-NINTH DEFENSE

Plaintiff's Unfair Practices Act claim is barred as a matter of law because such a claim based on the allegations in the Complaint is not actionable under the New Mexico Unfair Practices Act.

FORTIETH DEFENSE

To the extent not stated above, Sotera Health raises all applicable affirmative defenses applicable under New Mexico law.

FORTY-FIRST DEFENSE

Sotera Health is a holding company formed in 2004 that has never owned or operated the Facility or used or emitted ethylene oxide and therefore cannot have any liability in this case.

FORTY-SECOND DEFENSE

Sotera Health is a legally distinct company from Sterigenics U.S. under the law and cannot have liability for Sterigenics U.S.'s operations of the Facility and Plaintiff's allegations concerning those operations.

RESERVATION OF DEFENSES

Sotera Health hereby gives notice that it intends to rely upon such other defenses that are or may become available or apparent during the course of discovery and reserves the right to add or amend these defenses as discovery proceeds.

DEMAND FOR TWELVE-PERSON JURY

Sotera Health by and through the undersigned counsel, and pursuant to N.M. R. Civ. P. Dist. Ct. 1-038, hereby demands a trial by jury of twelve competent and impartial jurors be had on all triable issues in this case.

WHEREFORE, having answered Plaintiff's Complaint as specified herein, Sotera Health prays as follows:

- (a) Judgment in its favor on each and every Count contained in Plaintiff's Complaint;

- (b) That Plaintiff take nothing by reason of its Complaint;
- (c) That all costs of the action, including reasonable attorneys' fees, be taxed upon Plaintiff;
- (d) That a trial by a jury of twelve be had on all triable issues in this case; and
- (e) That this Court grant Sotera Health such other and further relief as the Court deems just, equitable, and proper.

[signature on following page]

Signed this 28th day of March, 2022.

MODRALL, SPERLING, ROEHL, HARRIS
& SISK, P.A.

By: /s/ Jeremy K. Harrison

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WE HEREBY CERTIFY that a true and correct copy of the foregoing was submitted through the Odyssey Electronic Filing System for filing and service to all counsel of record this 28th day of March 2022.

MODRALL, SPERLING, ROEHL, HARRIS
& SISK, P.A.

By: /s/ Jeremy K. Harrison
Jeremy K. Harrison